

COPY OF PAPERS
ORIGINALLY FILED

PATENT
18810-82002

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Steven L. Wechsler, Anthony B. Nesburn, Guey-Chuen Perng,
John S. Yu and Keith L. Black
Serial No. Unassigned
Filed: October 29, 2001
For: A HERPES SIMPLEX VIRUS TYPE 1 (HSV-1)-DERIVED
VECTOR FOR SELECTIVELY INHIBITING MALIGNANT
CELLS AND FOR EXPRESSING DESIRED TRAITS IN
MALIGNANT AND NON-MALIGNANT MAMMALIAN
CELLS

TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT

BOX PATENT APPLICATION
Assistant Commissioner for Patents
Washington, D. C. 20231

CERTIFICATE OF EXPRESS MAILING		
<small>HEREBY CERTIFY THAT THIS PAPER OR FEE IS BEING DEPOSITED WITH THE UNITED STATES POSTAL SERVICE "EXPRESS MAIL POST OFFICE TO ADDRESSEE" SERVICE UNDER 37 CFR 1.10 ON THE DATE AND LABEL INDICATED BELOW AND IS ADDRESSED TO BOX PATENT APPLICATION, THE ASSISTANT COMMISSIONER FOR PATENTS, WASHINGTON, D. C. 20231--</small>		
OCTOBER 29, 2001	<i>Shirley Dow</i>	EL 73 915 967 US
Date of Deposit	Signature SHIRLEY DOW	Express Label No.

Dear Sir:

Applicant's attorney submits herewith copies of the patents and/or other literature of which he is aware, that he believes may be material to the examination of this application and in respect of which there may be a duty to disclose in accordance with 37 C.F.R. § 1.56.

Applicant's attorney further submits herewith Form PTO-1449, "Information Disclosure Statement" by Applicant. A copy of each of the disclosed patent references and other references listed as other documents Nos. 1-47 is not being submitted herewith, because under Rule 37 C.F.R. § 1.98(d) this art was previously cited by the Examiner and/or the Applicant in connection with U.S. Serial No. 09/299,817, filed April 26, 1999. This previously filed Application was cited by applicant in this present Application per 35 U.S.C. §§ 120 and 119(e).

The filing of this information disclosure statement shall not be construed as a representation that a search has been made (37 C.F.R. 1.97(g)), an admission that the information cited is, or is considered to be, material to patentability or that no other material information exists (37 C.F.R. 1.97(h)). Further the filing of this information disclosure statement shall not be construed as an admission against interest in any manner.

The filing of this Information Disclosure Statement is before a first Office Action, therefore no fee is believed to be due. However, the Commissioner is hereby authorized to credit overpayments or charge any fees required to Deposit Account No. 50-1597 under 37 C.F.R. 1.16 or C.F.R. 1.17.

Respectfully submitted,

By: 

Nisan A. Steinberg, Ph.D.
Registration No. 40,345

SIDLEY AUSTIN BROWN & WOOD
555 West Fifth Street
Los Angeles, California 90013-1010
Ofc: 213/896-6665
Fax: 213/896-6600

INFORMATION DISCLOSURE STATEMENT
(Use several sheets if necessary)

ATTY DOCKET NO.
18810-82002

SERIAL NO.
unassigned

STEVEN L. WECHSLER ET AL.

FILING
Here with

GROUP

U.S. PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	4,769,331	09/06/88	ROIZMAN ET AL			
	4,859,587	08/22/89	ROIZMAN			
	5,288,641	02/22/94	ROIZMAN			
	5,328,688	07/12/94	ROIZMAN			
	5,585,096	12/17/96	MARTUZA ET AL.			
	5,599,691	02/04/97	ROIZMAN			
	5,670,477	09/23/97	PODUSLO ET AL.			
	5,728,379	03/17/98	MARTUZA ET AL.			

FOREIGN PATENT DOCUMENTS

	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
						YES	NO

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

1.	Barnett, F. H., "Selective delivery of herpes virus vectors to experimental brain tumors using RMP-7, Cancer Gene ther, 6(1):14-20 (Jan-Feb. 1999). ABSTRACT ONLY.
2.	Bi, Wan Li et al., "In Vitro Evidence that Metabolic Cooperation is Responsible for the Bystander Effect Observed with HSV tk Retroviral Gene Therapy," Human Gene Therapy, 4:725-731 (1993).

EXAMINER	DATE CONSIDERED
----------	-----------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

INFORMATION DISCLOSURE STATEMENT
(Use several sheets if necessary)

Docket Number (Optional)
18810-8200

Application Number
Unassigned

Applicant(s)
STEVEN L. WECHSLER ET AL.

Filing Date
Herewith

Group Art Unit

*EXAMINER INITIAL	OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)
	3. Boviatsis, E. J. et al., "Long-term survival of rats harboring brain neoplasms treated with ganciclovir and a herpes simplex virus vector that retains an intact thymidine kinase gene," Cancer Res, 54(22):5745-51, (Nov 15, 1994). ABSTRACT ONLY.
	4. Culver, Kenneth W., "Clinical Applications of Gene Therapy for Cancer," Clinical Chemistry, Vol. 40, N90. 4, pp. 510-12, (1994).
	5. Doran, S. E. et al., "Gene expression from recombinant viral vectors in the central nervous system after blood-brain barrier disruption," Neurosurgery, 36(5):965-70, (May 1995). ABSTRACT ONLY
	6. Kramm, C. M. et al., "Herpes vector-mediated delivery of marker genes to disseminated central nervous system tumors," Hum Gene Ther, 7(3):291-300, (Feb 10, 1996). ABSTRACT ONLY.
	7. Kramm, C. M. et al., "Therapeutic efficiency and safety of a second-generation replication-conditional HSV1 vector for brain tumor gene therapy," Hum Gene Ther, 8(17):2057-68, (Nov 20, 1997). ABSTRACT ONLY.
	8. Kroll, R. A. et al., "Improving drug delivery to intracerebral tumor and surrounding brain in a rodent model: a comparison of osmotic versus bradykinin modification of the blood-brain and/or blood-tumor barriers, Neurosurgery, 43(4):879-86; discussion 886-9, (Oct 1998). ABSTRACT ONLY.
	9. Markert, James M. et al., "Expanded spectrum of viral therapy in the treatment of nervous system tumors," J. Neurosurg, 77:590-594 (1992).
	10. Markert, James M. et al., "Reduction and Elimination of Encephalitis in an Experimental Glioma Therapy Model with Attenuated Herpes Simplex Mutants that Retain Susceptibility to Acyclovir," Neurosurgery, Vol. 32, No. 4, pp. 597-603, (April 1993).
	11. Martuza, Robert L., "Experimental Therapy of Human Glioma by Means of a Genetically Engineered Virus Mutant," Science, Vol. 252, pp. 854-856 (May 10, 1991).
	12. Mineta, Toshihiro et al., "Mutant Viral Therapy for Malignant Brain Tumors Using Ribonucleotide Reductase-Deficient Herpes Simplex Virus 1," J. Neurosurg., Vol. 80, No. 2, p. 381 (Feb 10, 1994). Meeting Program Item #1534.
	13. Moore, Alice E., "Effects of Viruses on Tumors," Annual Review of Microbiology, Vol. 8, pp. 393-410 (1954).
	14. Moore, A. E., "The Oncolytic Viruses," Experimental Tumor Research/Sloan-Kettering Institute for Cancer Research, 1:411-439, (1960)
EXAMINER	DATE CONSIDERED

*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP Section 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

INFORMATION DISCLOSURE STATEMENT

(Use several sheets if necessary)

Docket Number (Optional)

18810-82002

Application Number

Unassigned

Applicant(s)

STEVEN L. WECHSLER ET AL.

Filing Date

Herewith

Group Art Unit

*EXAMINER

INITIAL

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

15. Muldoon, L. L. et al., "Comparison of intracerebral inoculation and osmotic blood-brain barrier disruption for delivery of adenovirus, herpesvirus, and iron oxide particles to normal rat brain," Am J Pathol, 147(6):1840-51 (Dec 1995). ABSTRACT ONLY.
16. Nilaver, G. et al., "Delivery of herpesvirus and adenovirus to nude rat intracerebral tumors after osmotic blood-brain barrier disruption," Proc Natl Acad Sci U S A, 92(21):9829-33 (Oct 10, 1995). ABSTRACT ONLY.
17. Muldoon, L. L. et al., "A physiological barrier distal to the anatomic blood-brain barrier in a model of transvascular delivery," AJNR Am J Neuroradiol, 20(2):217-22 (Feb 1999). ABSTRACT ONLY.
18. Neuweil, E. A. et al., "Delivery of ultraviolet-inactivated 35S-herpesviruses across an osmotically modified blood-brain barrier," J Neurosurg, 74(3):475-9 (Mar 1991). ABSTRACT ONLY
19. Neuweil, E. A. et al., "Delivery of virus-sized iron oxide particles to rodent CNS neurons," Neurosurgery, 34(4):777-84 (Apr 1994). ABSTRACT ONLY.
20. Oldfield, Edward H. et al., Clinical Protocols, Gene Therapy for the Treatment of Brain Tumors Using Intra-Tumoral Transduction with Thymidine Kinase Gene and Intravenous Ganciclovir," Human Gene Therapy, 4:39-69 (1993).
21. Perng, G. C. et al., "Evidence that the HSV-1 LAT's Main Role May be in Reactivation from Latency Rather than in Establishment of Latency," Abstract presented at Association for Research in Vision and Ophthalmology (ARVO) May 1997.
22. Perng, Guey-Chuen et al., "The Latency-Associated Transcript Gene of Herpes Simplex virus Type 1 (HSV-1) Is Required for Efficient In Vivo Spontaneous Reactivation of HSV-1 from Latency," Journal of Virology, Vol. 68, No. 12, pp. 8045-8055 (Dec 1994)
23. Perng, Guey-Chuen et al., "An Avirulent ICP34.5 Deletion Mutant of Herpes Simplex virus Type 1 Is Capable of In Vivo Spontaneous Reactivation," Journal of Virology, Vol. 60, No. 5, pp. 3033-3041 (May 1995).
24. Perng, Guey-Chuen et al., "High-Dose Ocular Infection with a Herpes Simplex Virus Type 1 ICP34.5 Deletion Mutant Produces No Corneal Disease or Neurovirulence yet Results in Wild-Type Levels of Spontaneous Reactivation," Journal of Virology, Vol. 70, No. 5, pp. 2883-2893 (May 1996).
25. Rainov, N. G. et al. "Long-term survival in a rodent brain tumor model by bradykinin-enhanced intra-arterial delivery of a therapeutic herpes simplex virus vector," Cancer Gene Ther, 5(3):158-62 (May-Jun 1998). ABSTRACT ONLY.
26. Rainov, N. G. et al. "Intraarterial delivery of adenovirus vectors and liposome-DNA complexes to experimental brain neoplasms," Hum Gene Ther, 10(2):311-8 (Jan 20, 1999). ABSTRACT ONLY.

EXAMINER

DATE CONSIDERED

*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP Section 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

INFORMATION DISCLOSURE CITATION

(Use several sheets if necessary)

Docket Number (Optional)

18810-82002

Application Number

Unassigned

Applicant(s)

STEVEN L. WECHSLER ET AL.

Filing Date

Herewith

Group Art Unit

*EXAMINER
INITIAL

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

27.

Rainov, N. G. et al., "A chimeric fusion protein of cytochrome CYP4B1 and green fluorescent protein for detection of pro-drug activating gene delivery and for gene therapy in malignant glioma," Adv Exp Med Biol, 451:393-403 (1998). ABSTRACT ONLY.

28.

Rapoport, S. I., et al., "Tight-junctional modification as the basis of osmotic opening of the blood-brain barrier," Ann N Y Acad Sci, 481:250-67 (1986). ABSTRACT ONLY.

29.

Yang, W. et al., "Enhanced delivery of boronophenylalanine for neutron capture therapy by means of intracarotid injection and blood-brain barrier disruption," Neurosurgery, 38(5):985-92 (May 1996), ABSTRACT ONLY.

30.

Rainov, N. G. et al., "Selective uptake of viral and monocrystalline particles delivered intra-arterially to experimental brain neoplasms," 6(12):1543-52 (Dec 1995). ABSTRACT ONLY.

EXAMINER

DATE CONSIDERED

*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP Section 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

FORM PTO-1449 (Modified)

ATTY. DOCKET NO.

18810-82002

SERIAL NO.

Unassigned

SUPPLEMENTAL
LIST OF PATENTS AND PUBLICATIONS FOR
APPLICANT'S INFORMATION DISCLOSURE
STATEMENT

APPLICANT: Steven L. Wechsler et al.

FILING DATE: Herewith

GROUP ART UNIT: ---

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE
		5,112,596	05/12/92	Malfroy-Camine			
		5,268,164	12/07/93	Kozarich et al.			
		5,434,137	07/18/95	Black			
		5,527,778	06/18/96	Black			

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB CLASS	Translation	
							YES	NO

OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609;
Draw line through citation if not in conformance and not considered. Include copy of this form with next
communication to applicant.

FORM PTO-1449 (Modified) List of Patents and Publications for Applicants Information Disclosure Statement	ATTY DOCKET NO. 18810-82002	SERIAL NO. Unassigned
	APPLICANT: Wechsler et al.	
	FILING DATE: Herewith	GROUP ART UNIT ---

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB CLASS	TRANSLATION YES	TRANSLATION NO

OTHER ART (Including Author, title, Date, Pertinent Pages, Etc.)

	31.	Anderson, W.F., <i>Gene therapy scores against cancer</i> , Nat. Med. 6(8):862-63 [August 2000]
	32.	Delman, K.A. et al., <i>Effects of pre-existing immunity on the response to herpes simplex-based oncolytic viral therapy</i> , Human Gene Therapy 11:2465-72 [2000]
	33.	Ebbinghaus, C. et al., <i>Functional and selective targeting of adenovirus to high-affinity Fcγ receptor I-positive cells by using a bispecific hybrid adapter</i> , J. Virol. 75(1):480-489 [2001]
	34.	Haisma, H.J. et al., <i>Targeting of adenoviral vectors through a bispecific single-chain antibody</i> , Cancer Gene Ther. 7(6):901-04 [2000], Abstract only
	35.	Huard, J. et al., <i>Herpes simplex virus type 1 vector-mediated gene transfer to muscle</i> , Gene Ther. 2(6):385-92, Abstract only
	36.	Markert, J.M et al., <i>Conditionally replicating herpes simplex virus mutant, G207 for the treatment of malignant glioma: results of a phase I trial</i> , Gene Therapy 7:867-74 [2000]
	37.	Miller, C.R. et al., <i>Differential susceptibility of primary and established human glioma cells to adenovirus infection: targeting via the epidermal growth factor receptor achieves fiber receptor-independent gene transfer</i> , Cancer Res. 58:5738-5748 [1998]
	38.	Mullen, C.A. et al., <i>Molecular analysis of T lymphocyte-directed gene therapy for adenosine deaminase deficiency: long-term expression in vivo of genes introduced with a retroviral vector</i> , Human Gene Therapy 7:1123-1129 [June 1996]

EXAMINER	DATE CONSIDERED;
EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

List of Patents and Publications for Applicants Information Disclosure Statement	ATTY DOCKET NO. 18810-82002	SERIAL NO. Unassigned
	APPLICANT: Wechsler et al.	
	FILING DATE: Herewith	GROUP ART UNIT ---

OTHER ART (Including Author, title, Date, Pertinent Pages, Etc.)

39.	Nesburn, A.B. et al., <i>Therapeutic periocular vaccination with subunit vaccine induces higher levels of herpes simplex virus-specific tear secretory immunoglobulin A than systemic vaccination and provides protection against recurrent spontaneous ocular shedding of virus in latently infected rabbits</i> , Virology 252:200-09 [1998]
40.	Oyama, M et al., <i>Oncolytic viral therapy for human prostate cancer by conditionally replicating herpes simplex virus 1 vector G207</i> , Jpn. J. Cancer Res. 91(12):1339-44 [2000a], Abstract only
41.	Oyama, M. et al., <i>Intravesical and intravenous therapy of human bladder cancer by the herpes vector G207</i> , Hum. Gene Ther. 11(12):1683-93 [2000b], Abstract only
42.	Porada et al., <i>In utero gene therapy: transfer and long-term expression of the bacterial neor gene in sheep after direct injection of retroviral vectors into preimmune fetuses</i> , Human Gene Therapy 9:1571-85 [July 20, 1998]
43.	Toda, M. et al., <i>Herpes simplex virus as an in situ cancer vaccine for the induction of specific anti-tumor immunity</i> , Hum. Gene Ther. 10(3):385-93 [1999], Abstract only
44.	Walker, J.R. et al., <i>Local and systemic therapy of human prostate adenocarcinoma with the conditionally replicating herpes simplex virus vector G207</i> , Hum. Gene Ther. 10(13):2237-43 [1999], Abstract only

EXAMINER	DATE CONSIDERED;
EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

Date Mailed:

Page 8 of 8

FORM PTO-1449 (Modified) List of Patents and Publications for Applicants Information Disclosure Statement	ATTY DOCKET NO. 18810-82002	SERIAL NO. Unassigned
	APPLICANT: STEVEN L. WECHSLER, et al.	
	FILING DATE: Herewith	GROUP ART UNIT: ---

U.S. PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB CLASS	TRANSLATION YES	TRANSLATION No
	WO 92/13943	Aug. 20, 1992	PCT				

OTHER ART (Including Author, title, Date, Pertinent Pages, Etc.)

45.	International Search Report, PCT/US 00/11031, mailed Sept. 4, 2000.
46.	McGeoch, Duncan J., et al., Comparative sequence analysis of the long repeat regions and adjoining parts of the long unique regions in the genomes of herpes simplex viruses types 1 and 2, <u>Journal of General Virology</u> , Vol. 72: pp. 3057-3075 (1991).
47.	Kramm, Christof M., et al., <u>Gene Therapy for Brain Tumors</u> , Brain Pathology, Vol. 5: pp. 345-381 (1995).

EXAMINER	DATE CONSIDERED
EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	